

REMARKS

Claims 31, 34-42, and 60-64 were pending in this application. Claims 31 and 37 are amended. After entry of this amendment, claims 31, 34-42, and 60-64 will be pending in this application. Applicants submit that these amendments add no new matter.

Interview Summary

Applicants would like to thank Examiner Yabut for her time and helpful suggestions during the telephonic interview of September 21, 2007. Therein, Applicants discussed with the Examiner the rejection of claim 31 in view of Roue and claim 37 in view of Das. However, no agreement was reached.

Amendments to the Claims

Independent claim 31 is amended to recite introducing a hole through the septum primum from the right atrial side of the septum primum to the left atrial side of the septum primum. Support for this amendment is found in the application as originally filed, for example, at lines 7-10 of paragraph 71 and at lines 14-17 of paragraph 74, and in FIGS. 10A-C. Claim 31 is further amended to recite that the first flexible member is introduced through the opening of the patent foramen ovale from the right atrial side to the left atrial side. Support for this amendment is found in the application as originally filed, for example, at lines 7-10 of paragraph 71 and at lines 14-17 of paragraph 74, and in FIGS. 9 and 10A-C.

Independent claim 37 is amended to recite withdrawing the delivery member including said plurality of hexagonally shaped flexible members from the heart. Support for this amendment is found in the application as originally filed, for example, at lines 1-3 of paragraph 79 and at lines 4-6 of paragraph 81 and FIG. 13.

Claim Rejections under 35 U.S.C. § 102

Claim 37 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,334,217 to Das (“Das”). Applicants traverse the rejection to the extent it is maintained over the claim as amended.

It is well known law that in order for a claim to be anticipated, each and every element set forth in the claim must be found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053.

Applicants submit that Das is an improper reference under 35 U.S.C. 102(b) at least because Das does not teach each of the claimed steps of introducing at least one hexagonally shaped flexible member through the opening of a patent foramen ovale; contacting *the at least one* hexagonally shaped flexible member with the septum primum on the left atrial side; and withdrawing *the at least one* hexagonally shaped flexible member from the left atrial side. In other words, Das fails to teach a hexagonally shaped flexible member that is *introduced* through the opening of the patent foramen ovale, that the same hexagonally flexible member *contacts* the tissue of the septum primum on the left atrial side, and that the same hexagonally shaped flexible member is *withdrawn* from the left atrial side.

Das teaches a septal defect closure device (10) including two disks (20, 30) (col. 4, lines 53-55 and lines 62-63). As shown in FIGS. 8-10, Das' septal defect closure device (10) is delivered to close a septal defect via a catheter (C). According to Das, a distal tip of Das' catheter is extended through the defect to position the distal tip of the catheter on the distal side of the defect (FIG. 8; col. 11, lines 64-66). The first disk 20 of Das' septal defect closure device is deployed to "engage the distal side of the septum" (col. 12, lines 14-15). The catheter "retains[s] [Das'] second disk 30 within the catheter until the first disk engages the distal side of the septum" (col. 12, lines 12-15). The second disc 30 may then be urged out of the distal end of the catheter on the *proximal* side of the defect. (col. 12, lines 19-21; emphasis added). In other words, the *first* disk that engages the distal side of the septum is never removed from the distal side of the septum. Only the second disc, which never contacts the distal side of the septum, is urged onto the proximal side of the septum.

FIG. 9 shows deployment of Das' "first disk [20] [to] engage the distal side of the septum" (col. 12, lines 7-18). Das does not show or disclose that Das' first disk 20 is withdrawn from the distal side of the septum after engagement. In contrast, Applicants' claimed method requires that Applicants' hexagonally shaped flexible member contact the tissue of the septum primum on the left atrial side and be withdrawn from the left atrial side.

Furthermore, as shown in FIGS. 9-10 and described at col. 12, lines 24-33, Das' second disk cannot possibly contact the left atrial side of the septum as required by Applicants' claimed method because Das' second disk 30 is never deployed on the distal side of the septum.

Accordingly, even if Das' second disk 30 is introduced through the opening of a patent foramen ovale while maintained within the catheter and is withdrawn from the distal side of the septum while maintained within the catheter, Das does not teach that the second disk 30 contacts the distal side of the septum. Again, Applicants' claimed invention requires that the hexagonally shaped flexible member contact the tissue of the septum primum on the left atrial side and be withdrawn from the left atrial side.

Because Das' fails to teach that either of Das' disks (20, 30) contact and are withdrawn from the distal side of the septum, Applicants' submit that Das' teachings regarding Das' first or second disk (20, 30) cannot read on Applicants' claimed invention. Applicants' claimed invention requires that the at least one hexagonally shaped flexible member contacts the tissue of the septum primum on the left atrial side and is withdrawn from the left atrial side.

Further, Applicants' claimed method has been amended to require that the delivery member including the plurality of hexagonally shaped flexible members is withdrawn from the heart. In contrast to Applicants' claimed method, Das teaches that Das' septal defect closure device is permanently "anchored to the septum" to "prevent the flow of blood through the septum" so that the heart will operate normally (col. 4, lines 53-60; emphasis added). Accordingly, even if one of Das' disks (20, 30) contacts the left atrial side of the septum primum and is withdrawn from the left atrial side, Das is silent as to the either of Das' "anchored" disks (20, 30) being withdrawn from the heart as required by Applicants' claimed invention.

Because Das' fails to teach that Das' hexagonally shaped disks are withdrawn from the heart, Das' teachings cannot read on Applicants' claimed invention which requires withdrawing the delivery member including the plurality of hexagonally shaped flexible members from the heart.

For all these reasons, Applicants submit that Das fails to anticipate independent claim 37. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claim 37 under 35 U.S.C. 102(b).

Claim Rejections under 35 U.S.C. § 103

Claims 38-41, and 64 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Das in view of U.S. Patent No. 6,290,674 to Roue (“Roue”).

It is a well known principle of law that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981.

Claims 38-41 and 64 depend from claim 37. As previously discussed, claim 37 is patentable in view of Das because Das fails to disclose each and every limitation of claim 37. Applicants submit that claims 38-41 and 64 are therefore patentable at least for the same reasons that claim 37 is patentable.

Further, Roue fails to remedy the deficiencies of Das with respect to claim 37 as described above. Roue fails to teach introducing a hexagonally shaped flexible member through the opening of a patent foramen ovale, contacting the hexagonally shaped flexible member with the tissue of the septum primum of the patent foramen ovale on the left atrial side and withdrawing the hexagonally shaped flexible member from the heart. Rather, Roue is directed to a catheter for closing defects such as a patent foramen ovale with tissue anchors or patches (abstract, col. 15, lines 13-35). Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 38-41 and 64 under 35 U.S.C. § 103(a).

Claim 42 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Das in view of Roue and further in view of U.S. Patent No. 5,749,895 to Sawyer (“Sawyer”)

Claim 42 depends from claim 37. As previously discussed, claim 37 is patentable in view of Das because Das fails to disclose each and every limitation of claim 37. Applicants submit that claim 42 is therefore patentable at least for the same reasons that claim 37 is patentable.

Further, Roue and Sawyer fail to remedy the deficiencies of Das with respect to claim 37 as described above. Neither Roue nor Sawyer teaches introducing a hexagonally shaped flexible member through the opening of a patent foramen ovale, contacting the hexagonally shaped flexible member with the tissue of the septum primum of the patent foramen ovale on the left atrial side and withdrawing the hexagonally shaped flexible member from the heart. Rather,

Roue is directed to a catheter for closing defects such as a patent foramen ovale with tissue anchors and patches (abstract, col. 15, lines 13-35). Sawyer is directed to methods for fusing biological tissue, for example, by applying a patch with heat energy (col. 2, lines 39-42). Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 42 under 35 U.S.C. § 103(a).

Claims 31, 34-35, and 60-63 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Roue. Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claim 31 has been amended to recite introducing the second free end portion of the first flexible member through the opening of the patent foramen ovale from the right atrial side to the left atrial side. Claim 31 has been further amended to recite introducing a hole through the septum primum from the right atrial side of the septum primum to the left atrial side of the septum primum.

The Office action asserts that the teachings of Roue read on Applicants' claimed method. Applicants' respectfully disagree.

Applicants' submit that Roue teaches a catheter for closing an opening in a tissue (col. 3, lines 12-13). The distal end of the catheter 36 carries a series of anchor supports 62 that each have a proximal section 70, a distal section 72, and a flex point 74. The distal section 72 houses an introducer assembly 96 that houses a tissue anchor 90 (col. 11, lines 21-35). The tissue anchors 90 are designed for introduction into target tissue (col. 11, lines 66-67). The tip of the closure catheter 36 may also carry a detachable clamp 124 for closing a defect with sutures (col. 14, lines 51-56).

The Office action suggests that Applicants' claimed invention is disclosed in FIGS. 12-15 of Roue, in particular that the step of "introducing a hole through said septum primum" is disclosed in FIG. 13. Applicants claimed method requires that the direction in which a hole is made in the septum is from right atrium to left atrium and introduction of the first flexible member through the patent foramen ovale is from right atrium to left atrium. In other words, the claimed method requires that the hole formation step and the introducing step are both in the same direction. Applicants' submit that FIGS. 12-15 of Roue fail to teach introducing the

second free end portion of the first flexible member through the opening of the patent foramen ovale from the right atrial side to the left atrial side *and* introducing a hole through the septum primum in the *same* direction, *i.e.*, from the right atrial side of the septum primum to the left atrial side of the septum primum.

As shown in FIGS. 12 and 13, Roue's catheter is introduced through an aperture 122. FIG. 13 also depicts puncturing devices piercing the tissue 120 surrounding the aperture 122. Roue is silent with respect to the direction Roue's device moves. Assuming for the sake of argument that the right side of FIG. 13 is the right atrium and the left side of FIG. 13 is the left atrium, then Roue's catheter is depicted in FIG. 13 as being introduced through the patent foramen ovale from the right atrial side to the left atrial side.

However, keeping with the assumption that the right side of FIG. 13 is the right atrium and the left side of FIG. 13 is the left atrium, then Roue's puncture devices, as shown in FIG. 13, puncture the tissue from the left atrial side to the right atrial side, *i.e.*, not in the same direction as the introducing step required by Applicant's claimed method, rather in a direction that is opposite the direction required by Applicants' claimed invention. Accordingly, FIG. 13 of Roue fails to teach a required element of Applicant's claimed method. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 31 under section 103.

Claims 34-35 and 60-63 are dependent from claim 31. Accordingly, Applicants submit that claims 34-35 and 60-63 are patentable at least for the reasons that claim 31 is patentable.

For all these reasons, Applicants respectfully request that the rejection of claims 31, 34-35, and 60-63 under 35 U.S.C. 103(a) in view of Roue be reconsidered and withdrawn.

Claim 36 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Roue in view of Sawyer.

Claim 36 depends from claim 31. As previously discussed, claim 31 is patentable in view of Roue because Roue fails to disclose each and every limitation of claim 31. Applicants submit that claims 36 is therefore patentable at least for the same reasons that claim 31 is patentable.

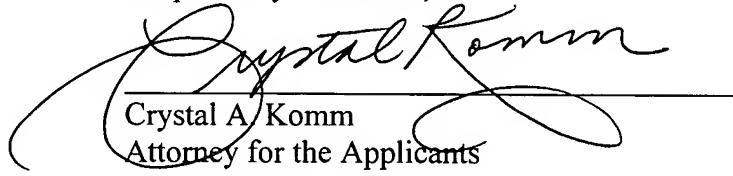
Sawyer fails to remedy the deficiencies of Roue as described above. Sawyer does not teach introducing a flexible member through a patent foramen ovale, contacting the left atrial

side of the tissue of the septum primum with a flexible member, or puncturing the septum from the right atrial side to the left atrial side. Rather, Sawyer is directed to methods for fusing biological tissue, for example, by applying a patch with heat energy (col. 2, lines 39-42). Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 36 under 35 U.S.C. § 103(a).

CONCLUSION

Applicants submit that the pending claims are in condition for allowance. Applicants respectfully request that the Examiner telephone the undersigned attorney to discuss this paper prior to issuing a further Office action.

Respectfully submitted,



Crystal A. Komm
Attorney for the Applicants

Kirkpatrick & Lockhart Preston Gates Ellis LLP
State Street Financial Center
One Lincoln Street
Boston, Massachusetts 02111-2950

Date: October 29, 2007
Limited Recognition No.: L0363

Tel. No.: (617) 261-3237
Fax No.: (617) 261-3175

BOS-1126098 v4